

ORAMED PHARMACEUTICALS INC.  
Form 10-Q  
January 12, 2012

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934

For the quarterly period ended November 30, 2011

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 000-50298

ORAMED PHARMACEUTICALS INC.  
(Exact Name of Registrant as Specified in its Charter)

Delaware 98-0376008  
(State or Other Jurisdiction of (IRS Employer Identification  
Incorporation or Organization) No.)

Hi-Tech Park 2/5 Givat Ram  
PO Box 39098  
Jerusalem, Israel 91390  
(Address of Principal (Zip Code)  
Executive Offices)

+ 972-2-566-0001  
(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T

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(§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

|                         |  |                           |                                     |
|-------------------------|--|---------------------------|-------------------------------------|
| Large accelerated filer | <input type="checkbox"/>   | Accelerated filer         | <input type="checkbox"/>            |
| Non-accelerated filer   | <input type="checkbox"/> (Do not check if a smaller reporting company) | Smaller reporting company | <input checked="" type="checkbox"/> |

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

As of January 10, 2012 there were 70,187,583 shares of the issuer's Common Stock, \$.001 par value, outstanding.

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ORAMED PHARMACEUTICALS INC.

FORM 10-Q

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PART I – FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

ORAMED PHARMACEUTICALS INC.  
(A development stage company)

CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

AS OF NOVEMBER 30, 2011

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ORAMED PHARMACEUTICALS INC.  
(A development stage company)

CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

AS OF NOVEMBER 30, 2011

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ORAMED PHARMACEUTICALS INC.  
(A development stage company)  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(UNAUDITED)  
U.S. dollars

|   | November<br>30,<br>2011 | August 31,<br>2011 |
|---|-------------------------|--------------------|
| <b>A s s e t s</b>  |                         |                    |
| <b>CURRENT ASSETS:</b>  |                         |                    |
| Cash and cash equivalents   | \$1,495,615             | \$1,513,365        |
| Short term deposits   | 1,805,030               | 1,801,400          |
| Marketable securities   | 380,359                 | 384,565            |
| Restricted cash   | 16,000                  | 16,000             |
| Accounts receivable - other   | 86,000                  | 542,891            |
| Prepaid expenses  | 18,519                  | 1,670              |
| Grants receivable from the Chief Scientist  | 63,961                  | 24,191             |
| T o t a l current assets  | 3,865,484               | 4,284,082          |
| LONG TERM DEPOSITS AND INVESTMENT   | 11,290                  | 10,186             |
| AMOUNTS FUNDED IN RESPECT OF EMPLOYEE RIGHTS UPON<br>RETIREMENT   | 14,469                  | 14,293             |
| PROPERTY AND EQUIPMENT, net   | 11,334                  | 17,376             |
| T o t a l assets  | \$3,902,577             | \$4,325,937        |
| <b>Liabilities and stockholders' equity</b>   |                         |                    |
| <b>CURRENT LIABILITIES:</b>   |                         |                    |
| Accounts payable and accrued expenses   | \$357,282               | \$375,538          |
| Related parties   | 19,838                  | 18,502             |
| Account payable with former shareholder   | 47,252                  | 47,252             |
| T o t a l current liabilities   | 424,372                 | 441,292            |
| <b>LONG TERM LIABILITIES:</b>   |                         |                    |
| Employee rights upon retirement   | 22,763                  | 22,675             |
| Provision for uncertain tax position  | 138,054                 | 138,054            |
|   | 160,817                 | 160,729            |
| <b>COMMITMENTS (note 2)</b>   |                         |                    |
| <b>STOCKHOLDERS' EQUITY:</b>  |                         |                    |
| Common stock of \$ 0.001 par value - authorized: 200,000,000<br>shares at November 30, 2011 and August 31, 2011; issued and<br>outstanding: 70,104,583 shares at November 30, 2011 and at August 31, 2011 | 70,104                  | 70,104             |
| Accumulated other comprehensive loss  | (4,221 )                | -                  |
| Additional paid-in capital  | 18,277,307              | 18,201,111         |
| Deficit accumulated during the development stage  | (15,025,802)            | (14,547,299)       |
| T o t a l stockholders' equity  | 3,317,388               | 3,723,916          |
| T o t a l liabilities and stockholders' equity  | \$3,902,577             | \$4,325,937        |

The accompanying notes are an integral part of the consolidated financial statements.

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ORAMED PHARMACEUTICALS INC.  
(A development stage company)  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATION  
(UNAUDITED)  
U.S. dollars

|   | Three months ended   |                      | Period<br>from April<br>12, 2002<br>(inception)<br>through |
|---|----------------------|----------------------|--|
|   | November 30,<br>2011 | November 30,<br>2010 | November 30,<br>2011                                       |
| RESEARCH AND DEVELOPMENT EXPENSES, net  | \$ 184,016           | \$ 286,488           | \$ 8,035,865   |
| IMPAIRMENT OF INVESTMENT  | -                    | -                    | 434,876  |
| GENERAL AND ADMINISTRATIVE EXPENSES   | 281,901              | 315,129              | 7,240,284  |
| OPERATING LOSS  | 465,917              | 601,617              | 15,711,025   |
| FINANCIAL INCOME  | (6,954 )             | (2,189 )             | (201,002 )   |
| FINANCIAL EXPENSE   | 19,556               | 3,356                | 200,813  |
| GAIN ON SALE OF INVESTMENT  | -                    | -                    | (1,033,004 )   |
| IMPAIRMENT OF AVAILABLE- FOR-SALE<br>SECURITIES   | -                    | -                    | 197,412  |
| LOSS BEFORE TAXES ON INCOME   | 478,519              | 602,784              | 14,875,244   |
| TAXES ON INCOME   | -                    | -                    | 150,558  |
| NET LOSS FOR THE PERIOD   | \$ 478,519           | \$ 602,784           | \$ 15,025,802  |
| <b>LOSS PER COMMON SHARE:</b>   |                      |                      |  |
| Basic and diluted   | \$ 0.01              | \$ 0.01              |  |
| <b>WEIGHTED AVERAGE NUMBER OF<br/>BASIC AND DILUTED SHARES USED<br/>IN COMPUTATION OF LOSS PER SHARE:</b> |                      |                      |  |
|   | 70,104,583           | 57,932,597           |  |

The accompanying notes are an integral part of the consolidated financial statements.



ORAMED PHARMACEUTICALS INC.  
(A development stage company)  
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY  
(UNAUDITED)  
U.S. dollars

|   | Common Stock<br>Shares | \$        | Additional<br>paid-in<br>capital | Deficit<br>accumulated<br>during the<br>development<br>stage | Other<br>comprehensive<br>loss | Total<br>stockholders'<br>equity |
|---|------------------------|-----------|----------------------------------|--|--------------------------------|----------------------------------|
| BALANCE AS OF APRIL<br>12, 2002 (inception)   | 34,828,200             | \$34,828  | \$18,872                         |  |                                | \$53,700                         |
| CHANGES DURING THE<br>PERIOD FROM APRIL<br>12, 2002 THROUGH<br>AUGUST 31, 2010 :              |                        |           |                                  |  |                                |                                  |
| SHARES CANCELLED  | (19,800,000)           | (19,800 ) | 19,800                           |  |                                | -                                |
| SHARES ISSUED FOR<br>INVESTMENT IN ISTI-NJ  | 1,144,410              | 1,144     | 433,732                          |  |                                | 434,876                          |
| SHARES ISSUED FOR<br>OFFERING COSTS   | 1,752,941              | 1,753     | (1,753 )                         |  |                                | -                                |
| SHARES AND<br>WARRANTS ISSUED<br>FOR CASH- NET OF<br>ISSUANCE EXPENSES                        | 37,359,230             | 37,359    | 7,870,422                        |  |                                | 7,907,781                        |
| SHARES ISSUED<br>FOR SERVICES   | 1,730,540              | 1,731     | 819,606                          |  |                                | 617,638                          |
| CONTRIBUTIONS TO<br>PAID IN CAPITAL   |                        |           | 18,991                           |  |                                | 18,991                           |
| RECEIPTS ON<br>ACCOUNT OF SHARES<br>AND WARRANTS  |                        |           | 6,061                            |  |                                | 6,061                            |
| SHARES ISSUED FOR<br>CONVERSION OF<br>CONVERTIBLE NOTE  | 550,000                | 550       | 274,450                          |  |                                | 275,000                          |
| STOCK BASED<br>COMPENSATION<br>RELATED TO OPTIONS<br>GRANTED TO<br>EMPLOYEES AND<br>DIRECTORS |                        |           | 3,554,921                        |  |                                | 3,554,921                        |
| STOCK BASED<br>COMPENSATION<br>RELATED TO OPTIONS<br>GRANTED TO<br>CONSULTANTS                |                        |           | 615,882                          |  |                                | 615,882                          |
| DISCOUNT ON<br>CONVERTIBLE NOTE   |                        |           | 108,000                          |  |                                | 108,000                          |

|   |            |          |              |                |             |              |
|---|------------|----------|--------------|----------------|-------------|--------------|
| RELATED TO<br>BENEFICIAL<br>CONVERSION FEATURE<br>OTHER<br>COMPREHENSIVE LOSS                 |            |          |              |                | (16 )       | (16 )        |
| IMPUTED INTEREST  |            |          | 19,777       |                |             | 19,777       |
| NET LOSS  |            |          |              | (12,986,038)   |             | (12,986,038) |
| BALANCE AS OF<br>AUGUST 31, 2010  | 57,565,321 | 57,565   | 13,758,761   | (12,986,038)   | (16 )       | 830,272      |
| SHARES ISSUED<br>FOR SERVICES<br>RENDERED   | 730,636    | 731      | 226,838      |                |             | 227,569      |
| SHARES AND<br>WARRANTS ISSUED<br>FOR CASH   | 11,808,626 | 11,808   | 3,682,404    |                |             | 3,694,212    |
| STOCK BASED<br>COMPENSATION<br>RELATED TO OPTIONS<br>GRANTED TO<br>EMPLOYEES AND<br>DIRECTORS |            |          | 502,593      |                |             | 502,593      |
| STOCK BASED<br>COMPENSATION<br>RELATED TO OPTIONS<br>GRANTED TO<br>CONSULTANTS                |            |          | 26,733       |                |             | 26,733       |
| IMPUTED INTEREST  |            |          | 3,782        |                |             | 3,782        |
| NET LOSS  |            |          |              | (1,561,245 )   |             | (1,561,245 ) |
| BALANCE AS OF<br>AUGUST 31, 2011  | 70,104,583 | 70,104   | 18,201,111   | (14,547,283)   | (16 )       | 3,723,916    |
| SHARES TO BE ISSUED<br>FOR SERVICES   |            |          | 24,900       |                |             | 24,900       |
| STOCK BASED<br>COMPENSATION<br>RELATED TO OPTIONS<br>GRANTED TO<br>EMPLOYEES AND<br>DIRECTORS |            |          | 44,794       |                |             | 44,794       |
| STOCK BASED<br>COMPENSATION<br>RELATED TO OPTIONS<br>GRANTED TO<br>CONSULTANTS                |            |          | 6,502        |                |             | 6,502        |
| OTHER<br>COMPREHENSIVE<br>INCOME  |            |          |              |                | (4,205 )    | (4,205 )     |
| NET LOSS  |            |          |              | (478,519 )     |             | (478,519 )   |
| BALANCE AS OF<br>NOVEMBER 30, 2011  | 70,104,583 | \$70,104 | \$18,277,307 | \$(15,025,802) | \$ (4,221 ) | \$3,317,388  |



ORAMED PHARMACEUTICALS INC.  
(A development stage company)  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(UNAUDITED)  
U.S. dollars

|  | Three months ended   |              | Period from<br>April 12,<br>2002<br>(inception<br>date) through<br>November<br>30,<br>2011 |
|--|----------------------|--------------|--|
|  | November 30,<br>2011 | 2010         |  |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>   |                      |              |  |
| Net loss   | \$(478,519 )         | \$(602,784 ) | \$(15,025,802 )  |
| Adjustments required to reconcile net loss to net cash used in operating activities: |                      |              |  |
| Depreciation   | 6,042                | 7,451        | 112,149  |
| Amortization of debt discount  | -                    | -            | 108,000  |
| Exchange differences on deposits and investments                                     | (3,849 )             | (385 )       | (6,517 )   |
| Stock based compensation   | 51,296               | 195,301      | 4,751,425  |
| Shares issued for services rendered  | -                    | 88,800       | 1,048,096  |
| Shares to be issued for services rendered  | 24,900               |              | 24,900   |
| Gain on sale of investment   | -                    |              | (1,033,004 )   |
| Impairment of investment   | -                    | -            | 434,876  |
| Imputed interest   | -                    | 947          | 23,559   |
| Impairment of available for sale security  | -                    | -            | 197,412  |
| Changes in operating assets and liabilities:   |                      |              |  |
| Prepaid expenses and other current assets  | (49,727 )            | (111,494 )   | (167,685 )   |
| Restricted cash  | -                    | (9 )         | (16,000 )  |
| Accounts payable and accrued expenses  | (16,920 )            | (76,182 )    | 377,120  |
| Liability of employee rights upon retirement   | 88                   | -            | 22,763   |
| Provision for uncertain tax position   | -                    | -            | 138,054  |
| Total net cash used in operating activities  | (466,689 )           | (498,355 )   | (9,010,654 )   |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>   |                      |              |  |
| Purchase of property and equipment   | -                    | -            | (123,483 )   |
| Acquisition of short-term investments  | -                    | -            | (5,428,382 )   |
| Funds in respect of employee rights upon retirement                                  | (1,061 )             | -            | (15,354 )  |
| Proceeds from sale of investment in Entera   | 450,000              |              | 450,000  |
| Proceeds from sale of Short term investments   | -                    | 100,000      | 3,628,000  |
| Lease deposits, net  | -                    | -            | (7,509 )   |
| Total net cash derived from (used in) investing activities                           | 448,939              | 100,000      | (1,496,728 )   |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>   |                      |              |  |
| Proceeds from sales of common stock and warrants - net of issuance expenses          | -                    | 300,000      | 11,655,693   |
| Receipts on account of shares issuances  | -                    | -            | 6,061  |

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|   |                    |                    |                    |
|---|--------------------|--------------------|--------------------|
| Proceeds from convertible notes                                       | -                  | -                  | 275,000            |
| Proceeds from short term note payable                                 | -                  | -                  | 120,000            |
| Payments of short term note payable                                   | -                  | -                  | (120,000 )         |
| Shareholder advances  | -                  | -                  | 66,243             |
| Net cash provided by financing activities                             | -                  | 300,000            | 12,002,997         |
| <b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>               | <b>(17,750 )</b>   | <b>(98,355 )</b>   | <b>1,495,615</b>   |
| <b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>               | <b>1,513,365</b>   | <b>1,199,638</b>   | <b>-</b>           |
| <b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>                     | <b>\$1,495,615</b> | <b>\$1,101,283</b> | <b>\$1,495,615</b> |
| Non cash investing and financing activities:                          |                    |                    |                    |
| Shares issued for offering costs                                      | -                  | -                  | \$77,779           |
| Contribution to paid in capital                                       | -                  | -                  | \$18,991           |
| Discount on convertible note related to beneficial conversion feature | -                  | -                  | \$108,000          |

The accompanying notes are an integral part of the consolidated financial statements.

ORAMED PHARMACEUTICALS Inc.

(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES:

a.

General:

1. Oramed Pharmaceuticals Inc. (the “Company”) was incorporated on April 12, 2002, under the laws of the State of Nevada. From incorporation until March 3, 2006, the Company was an exploration stage company engaged in the acquisition and exploration of mineral properties. On February 17, 2006, the Company entered into an agreement with Hadasit Medical Services and Development Ltd (the “First Agreement”) to acquire the provisional patent related to orally ingestible insulin pill to be used for the treatment of individuals with diabetes. The Company has been in the development stage since its formation and has not yet realized any revenues from its planned operations.

On May 14, 2007, the Company incorporated a wholly-owned subsidiary in Israel, Oramed Ltd., which is engaged in research and development. Unless the context indicates otherwise, the term “Group” refers to Oramed Pharmaceuticals Inc. and its Israeli subsidiary, Oramed Ltd (the “Subsidiary”).

On March 11, 2011, the Company was reincorporated from the State of Nevada to the State of Delaware.

The Group is engaged in research and development in the biotechnology field and is considered a development stage company in accordance with ASC Topic 915 “Development Stage Entities”.

The accompanying unaudited interim consolidated financial statements as of November 30, 2011, have been prepared in accordance with accounting principles generally accepted in the United States relating to the preparation of financial statements for interim periods. Accordingly, they do not include all the information and footnotes required for annual financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair statement have been included. The accounting principles applied in the preparation of the interim statements are consistent with those applied in the preparation of the annual financial statements; however,- the interim statements do not include all the information and explanations required for the annual financial statements. The condensed consolidated balance sheet data as of August 31, 2011 was derived from the Company’s audited financial statements, but does not include all disclosures required by generally accepted accounting principles. For additional information, including the Company’s significant accounting policies, refer to the consolidated financial statements and related footnotes in the Company’s fiscal 2011 Annual Report on Form 10-K. Operating results for the three months ended November 30, 2011, are not necessarily indicative of the results that may be expected for the year ending August 31, 2012.

ORAMED PHARMACEUTICALS Inc.

(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

2. Going concern considerations

The accompanying unaudited interim consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company has net losses for the period from inception (April 12, 2002) through November 30, 2011 of \$15,025,802 as well as negative cash flow from operating activities. Presently, the Company does not have sufficient cash resources to meet its requirements in the twelve months following November 30, 2011. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management is in the process of evaluating various financing alternatives as the Company will need to finance future research and development activities and general and administrative expenses through fund raising in the public or private equity markets. Although there is no assurance that the Company will be successful with those initiatives, management believes that it will be able to secure the necessary financing as a result of ongoing financing discussions with third party investors and existing shareholders, as well as on going funding from the Office of the Chief Scientist of the Ministry of Industry, Trade and Labor of Israel ("OCS").

These consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern. The Company's continuation as a going concern is dependent on its ability to obtain additional financing as may be required and ultimately to attain profitability.

b. Newly issued and recently adopted Accounting Pronouncements

1. In May 2011, the FASB issued an accounting update that amends ASC 820 - "Fair Value Measurement" regarding fair value measurements and disclosure requirements. The amendments are effective during interim and annual periods beginning after December 15, 2011 and are to be applied prospectively. The accounting update will be applicable to the Company beginning in the third quarter of fiscal year 2012.

2. In June 2011, the FASB issued an update to Accounting Standards Codification (ASC) No. 220, "Presentation of Comprehensive Income," which eliminates the option to present other comprehensive income and its components in the statement of shareholders' equity. The Company can elect to present the items of net income and other comprehensive income in a single continuous statement of comprehensive income or in two separate, but consecutive, statements. Under either method the statement would need to be presented with equal prominence as the other primary financial statements. The amended guidance, which must be applied retroactively, is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, with earlier adoption permitted. In December 2011, the FASB issued another update on the topic, which deferred the effective date pertaining only to the presentation of reclassification adjustments on the face of the financial statements.

ORAMED PHARMACEUTICALS Inc.

(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

NOTE 2 - COMMITMENTS:

a. Under the terms of the First Agreement with Hadasit (note 1a above), the Company retained Hadasit to provide consulting and clinical trial services. As remuneration for the services provided under the agreement, Hadasit is entitled to \$200,000. The primary researcher for Hadasit is Dr. Miriam Kidron, a director and officer of the Company. The funds paid to Hadasit under the agreement are deposited by Hadasit into a research fund managed by Dr. Kidron. Pursuant to the general policy of Hadasit with respect to its research funds, Dr. Kidron receives from Hadasit a management fee in the rate of 10% of all the funds deposited into this research fund. The total amount paid to Dr. Kidron out of this fund was \$10,214.

On January 7, 2009, the Company entered into a second agreement with Hadasit (the "Second Agreement"). In the Second Agreement, Hadasit confirms that it has conveyed, transferred and assigned all of its ownership rights in the patents acquired under the First Agreement to the Company, and certain other patents filed by the Company after the First Agreement as a result of the collaboration between the Company and Hadasit.

On July 8, 2009 the Company entered into a third agreement with Hadasit, Prof. Itamar Raz and Dr. Miriam Kidron ("the Third Agreement"), to retain consulting and clinical trial services from Hadasit. According to the Third Agreement, Hadasit will be entitled to a total consideration of \$400,000 to be paid by Oramed. \$200,000 of this amount was agreed in the terms of the First Agreement, and the remaining of \$200,000 will be paid in accordance with the actual progress of the study. The total amount that was paid through November 30, 2011 was \$400,000.

On September 11, 2011, the Company entered into a fourth agreement with Hadasit, Dr. Miriam Kidron and Dr. Daniel Schurr ("the Fourth Agreement"), to retain consulting and clinical trial services. According to the Fourth Agreement, Hadasit will be entitled to a consideration of \$200,000 to be paid by Oramed. None of which was recognized or paid through November 30, 2011.

b. On September 19, 2007 the Subsidiary entered into a lease agreement for its office facilities in Israel. The lease agreement was for a period of 51 months, and ended on December 31, 2011. The monthly lease payment was NIS 2,396 and was linked to the increase in the Israeli consumer price index, (as of November 30, 2011 the monthly payment in the Company's functional currency is \$632, considering the fact that the remaining term for the current lease is one month, the Company's commitment for November 30, 2011 is \$ 632, however the Company is currently in the process of negotiation into a new lease agreement for the same premise.

As security for its obligation under this lease agreement the Company provided a bank guarantee in an amount equal to three monthly lease payments.



ORAMED PHARMACEUTICALS Inc.

(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

NOTE 2 - COMMITMENTS (continued):

- c. On April 21, 2009, the subsidiary entered into a consulting service agreement with ADRES Advanced Regulatory Services Ltd. ("ADRES") pursuant to which ADRES will provide consulting services relating to quality assurance and regulatory processes and procedures in order to assist the Subsidiary in submission of a U.S. IND according to FDA regulations. In consideration for the services provided under the agreement, ADRES will be entitled to a total cash compensation of \$211,000, of which the amount of \$110,000 will be paid as a monthly fixed fee of \$10,000 each month for 11 months commencing May 2009, and the remaining \$101,000 will be paid based on achievement of certain milestones. \$160,000 of the total amount was paid through November 30, 2011, \$50,000 of that were paid for completing the three first milestones, the rest will be paid during 2012, subject to the completion of the IND.
- d. On February 10, 2010, the Subsidiary entered into an agreement with Vetgenerics Research G. Ziv Ltd, a clinical research organization (CRO), to conduct a toxicology trial on its oral insulin capsules. The total cost estimated for the studies is €107,100 (\$142,522) of which €89,293 (\$118,825) was paid through November 30, 2011.
- e. On July 5, 2010, the Subsidiary of the Company entered into a Manufacturing Supply Agreement (MSA) with Sanofi-Aventis Deutschland GMBH ("sanofi-aventis"). According to the MSA, sanofi-aventis will supply the subsidiary with specified quantities of recombinant human insulin to be used for clinical trials in the USA.
- f. On February 15, 2011, the Subsidiary entered into a consulting agreement with a third party (the "Consultant") for a period of five years, pursuant to which the Consultant will provide consultation on scientific and clinical matters. The Consultant is entitled to a fixed monthly fee of \$8,000, royalties of 8% of the net royalties actually received by the Subsidiary in respect of the patent that was sold to Entera on February 22, 2011 and an option to purchase up to 250,000 shares of common stock, par value \$0.001 per share, of the Company at an exercise price of \$0.50 per share. The option vest in five annual installments commencing February 16, 2012 and expire on February 16, 2021. The initial fair value of the option on the date of grant was \$71,495, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 113.80%; risk-free interest rates of 3.42%; and the remaining contractual life of 10 years. The fair value of the options granted is measured on a final basis at the end of the related service period and is recognized over the related service period using the straight-line method.
- g. On May 13, 2011, the Company entered into a consulting agreement with a third party ("the Consultant") for a period of 12 months, pursuant to which the Consultant will provide investors relations services and will be entitled to a cash monthly fee of \$4,000, that may be increased up to \$10,000 upon the completion of a \$5,000,000 capital raise by the Company. In addition, the Consultant received a warrant to purchase up to 32,000 shares of the Company. The warrant has a term of five years and an exercise price of \$0.50 per Share and will vest in 12 installments in the period from October 2011 to May 2016. The Company records expenses in respect of this warrant during the term of the services.
- h. On June 22, 2011 the Subsidiary issued a purchase order to SAFC Pharma for producing one of its oral capsule ingredients in the amount of \$600,000, none of which was recognized or paid through November 30, 2011.



ORAMED PHARMACEUTICALS Inc.

(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

NOTE 2 - COMMITMENTS (continued):

i. On August 15, 2011, the Company entered into an advisory agreement with a third party ("the Advisor") for a period of nine months, pursuant to which the Advisor will provide investors relations services and will be entitled to a cash monthly fee of \$4,000, and additional \$3,000 in the first month. In addition, the Advisor will be issued 249,000 shares of the Company in three installments over the engagement period, commencing November 2011. See also note 4.

j. Grants from Bio-Jerusalem

The Subsidiary is committed to pay royalties to Bio-Jerusalem fund on proceeds from future sales at a rate of 4% and up to 100% of the amount of the grant received by the Company (Israeli CPI linked) at the total amount of \$52,733. As of November 30, 2011, the Subsidiary had not yet realized any revenues from the said project and did not incur any royalty liability.

For the three months period ended November 30, 2011, there were no grants received from the Bio-Jerusalem fund.

k. Grants from the Office of the Chief Scientist ("OCS")

The Subsidiary is committed to pay royalties to the Government of Israel on proceeds from sales of products in the research and development of which the Government participates by way of grants.

At the time the grants were received, successful development of the related projects was not assured. In case of failure of a project that was partly financed as above, the Subsidiary is not obligated to pay any such royalties.

Under the terms of the Subsidiary's funding from the Israeli Government, royalties of 3%-3.5% are payable on sales of products developed from a project so funded, up to 100% of the amount of the grant received by the Subsidiary (dollar linked) with the addition of annual interest at a rate based on LIBOR.

As of November 30, 2011, the Subsidiary had not yet realized any revenues from the said project and did not incur any royalty liability.

For the three months period ended November 30, 2011, the research and development expenses are presented net of OCS Grants, in the total amount of \$41,257.

ORAMED PHARMACEUTICALS Inc.

(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

NOTE 3 - FAIR VALUE:

The Company measures fair value and discloses fair value measurements for financial assets. Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The accounting standard establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
- Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.
- Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent.

Marketable securities consist wholly of equity securities of D.N.A Biomedical Solutions Ltd. which were received in March 2011 as part of the consideration for selling the Company's equity method investee Entera. Those securities are classified as available-for-sale and are recorded at fair value. The D.N.A Shares are listed on the Tel Aviv Stock Exchange ("TASE") and their tradability is restricted for a period of 6 months from the closing date of the transaction according to TASE policy with regards to private placements. Until September 30, 2011, the fair value of the restricted securities was measured based on the quoted prices of the otherwise identical unrestricted securities, adjusted for the effect of the restriction by applying a proper discount. The discount was determined with reference to other similar restricted instruments. Similar securities, with no restriction on tradability, are quoted on an active market. As of October 1, 2011, the securities are not restricted. The fair value of the securities is measured based on the quoted prices of the securities on an active market.

Transfers in and/or out of Level 3 are recognized in the beginning of the reporting period.

ORAMED PHARMACEUTICALS Inc.  
(A development stage company)  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

## NOTE 3 - FAIR VALUE (continued):

Financial items carried at fair value as of November 30, 2011 and August 31, 2011 are classified in the tables below in one of the three categories described above:

|                        | Fair value measurements at reporting<br>date using |         |            | Total      |
|------------------------|--|---------|------------|------------|
|                        | Level 1  | Level 2 | Level 3    |            |
| Marketable securities: |  |         |            |            |
| November 30, 2011      | \$ 380,359   | -       | -          | \$ 380,359 |
| August 31, 2011        | -  | -       | \$ 384,564 | \$ 384,564 |

The following table summarizes the activity for those financial assets where fair value measurements are estimated utilizing Level 3 inputs:

|   | Three months<br>ended<br>November, 30<br>2011<br>Unaudited |
|---|--|
| Carrying value at the beginning of the period | \$ 384,564   |
| Reclassification to level 1                   | (384,564 )   |
| Carrying value at the end of the period       | -  |

## NOTE 4 - SUBSEQUENT EVENT

On December 12, 2011 the Company issued 83,000 shares of its common stock to an advisory company as remuneration for services provided. The fair value of the shares at the date of grant was \$24,900. See also note 2i.

## ITEM 2 - MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with the financial statements and the related notes included elsewhere herein and in our consolidated financial statements, accompanying notes and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended August 31, 2011.

This Quarterly Report on Form 10-Q (including the section regarding Management's Discussion and Analysis of Financial Condition and Results of Operations) contains forward-looking statements regarding our business, financial condition, results of operations and prospects. Words such as "expects," "anticipates," "intends," "plans," "believes," "sees," "estimates" and similar expressions or variations of such words are intended to identify forward-looking statements, but are not deemed to represent an all-inclusive means of identifying forward-looking statements as denoted in this Quarterly Report on Form 10-Q. Additionally, statements concerning future matters are forward-looking statements.

Although forward-looking statements in this Quarterly Report on Form 10-Q reflect the good faith judgment of our management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include, without limitation, those specifically addressed under "Item 1A – Risk Factors" in our Annual Report on Form 10-K for the year ended August 31, 2011, and filed with the Securities and Exchange Commission (the "SEC" or the "Commission") on November 30, 2011, as well as those discussed elsewhere in our annual report and in this Quarterly Report on Form 10-Q. Readers are urged not to place undue reliance on these forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. We undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this Quarterly Report on Form 10-Q. Readers are urged to carefully review and consider the various disclosures made throughout the entirety of this Quarterly Report on Form 10-Q which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

As used in this Quarterly Report on Form 10-Q, the terms "we", "us", "our", the "Company", and "Oramed" mean Oramed Pharmaceuticals Inc. and our subsidiary, Oramed Ltd., unless otherwise indicated.

All dollar amounts refer to U.S. dollars unless otherwise indicated.

### Overview of Operations

We are a pharmaceutical company engaged in the research and development of innovative pharmaceutical solutions, including an orally ingestible insulin capsule or tablet to be used for the treatment of individuals with diabetes, use of orally ingestible capsules, tablets or pills for delivery of other polypeptides.

Oramed was incorporated on April 12, 2002, in the State of Nevada under the name Iguana Ventures Ltd. Following the incorporation, the Company was an exploration stage company engaged in the acquisition and exploration of mineral properties. The Company was unsuccessful in implementing its business plan as a mineral exploration company. Accordingly, the Company decided to change the focus of its business by completing a share exchange with the shareholders of Integrated Security Technologies, Inc., a New Jersey private corporation ("ISTI"). On June 4, 2004, the Company changed its name to Integrated Security Technologies, Inc. by filing a Certificate of Amendment with the Nevada Secretary of State. Effective June 14, 2004 the Company effected a 3.3:1 forward stock split, increasing the amount of authorized capital to 200,000,000 shares of common stock with the par value of \$0.001 per share. However, due to disappointing results of ISTI, on May 31, 2005, effective as of May 27, 2004 the Company terminated the share exchange agreement with the shareholders of ISTI.

On February 17, 2006, we executed an agreement with Hadasit Medical Services and Development Ltd. ("Hadasit") to acquire provisional patent application No. 60/718716 and related intellectual property. The provisional patent application No. 60/718716 relates to a method of preparing insulin so that it may be taken orally to be used in the treatment of individuals with diabetes. On April 10, 2006, we changed our name from Integrated Security Technologies, Inc. to Oramed Pharmaceuticals Inc. On August 31, 2006, based on provisional patent application No. 60/718716, we filed a patent application under the Patent Cooperation Treaty at the Israel Patent Office for "Methods and Compositions for Oral Administration of Proteins."

On March 11, 2011, Oramed was reincorporated from the State of Nevada to the State of Delaware.

#### Recent Business Developments

On September 11, 2011, we entered into a fourth agreement with Hadasit, Dr. Miriam Kidron and Dr. Daniel Schurr (the "Fourth Agreement"), to facilitate clinical trials and provide other services. According to the Fourth Agreement, Hadasit will be entitled to a consideration of \$200,000. The terms and conditions of the Fourth Agreement are substantially similar to those of the previous Hadasit agreements.

#### Short Term Business Strategy

We plan to conduct further research and development on the technology covered by the patent application "Methods and Composition for Oral Administration of Proteins", which we acquired from Hadasit, as well as the other patents we have filed since. Through our research and development efforts, we are seeking to develop an oral dosage form that will withstand the harsh chemical environment of the stomach and intestines and will be effective in delivering active insulin for the treatment of diabetes. The enzymes and vehicles that are added to the insulin in the formulation process must not modify the insulin chemically or biologically, and the dosage form must be safe to ingest. We plan to continue to conduct clinical trials to show the effectiveness of our technology. We intend to conduct the clinical trials necessary to file an Investigational New Drug ("IND") application with the U.S. Food and Drug Administration (the "FDA"). Additional clinical trials are planned in other countries such as Israel, India and South Africa, in order to substantiate our results as well as for purposes of making future filings for drug approval in these countries. We also plan to conduct further research and development by deploying our proprietary drug delivery technology for the delivery of other polypeptides in addition to insulin, and to develop other innovative pharmaceutical products.

## Long Term Business Strategy

If our oral insulin capsule or other drug delivery solutions show significant promise in clinical trials, we plan to ultimately seek a strategic commercial partner, or partners, with extensive experience in the development, commercialization, and marketing of insulin applications and/or other orally digestible drugs. We anticipate such partner or partners would be responsible for, or substantially support, late stage clinical trials (Phase III) to increase the likelihood of obtaining regulatory approvals and registrations in the appropriate markets in a timely manner. We further anticipate that such partner, or partners, would also be responsible for sales and marketing of our oral insulin capsule in these markets. Such planned strategic partnership, or partnerships, may provide a marketing and sales infrastructure for our products as well as financial and operational support for global clinical trials, post marketing studies, label expansions and other regulatory requirements concerning future clinical development in the United States and elsewhere. Any future strategic partner, or partners, may also provide capital and expertise that would enable the partnership to develop new oral dosage form for other polypeptides. While our strategy is to partner with an appropriate party, no assurance can be given that any third party would be interested in partnering with us. Under certain circumstances, we may determine to develop one or more of our oral dosage form on our own, either world-wide or in select territories.

## Other Planned Strategic Activities

In addition to developing our own oral dosage form drug portfolio, we are, on an on-going basis, considering in-licensing and other means of obtaining additional technologies to complement and/or expand our current product portfolio. Our goal is to create a well-balanced product portfolio that will enhance and complement our existing drug portfolio.

## Product Development

### Orally Ingestible Insulin

During fiscal year 2007 we conducted several clinical studies of our orally ingestible insulin. The studies were intended to assess both the safety/tolerability and absorption properties of our proprietary oral insulin. Based on the pharmacokinetic and pharmacologic outcomes of these trials, we decided to continue the development of our oral insulin product.

On November 15, 2007, we successfully completed animal studies in preparation for the Phase 1B clinical trial of our oral insulin capsule (ORMD0801). On January 22, 2008, we commenced the non-FDA approved Phase 1B clinical trials with our oral insulin capsule, in healthy human volunteers with the intent of dose optimization. On March 11, 2008, we successfully completed our Phase 1B clinical trials.

On April 13, 2008, we commenced a non-FDA approved Phase 2A study to evaluate the safety and efficacy of our oral insulin capsule (ORMD0801) in type 2 diabetic volunteers at Hadassah Medical Center in Jerusalem. On August 6, 2008, we announced the successful results of this trial.



In July 2008 we were granted approval by the Institutional Review Board Committee of Hadassah Medical Center in Jerusalem to conduct a non-FDA approved Phase 2A study to evaluate the safety and efficacy of our oral insulin capsule (ORMD0801) on type 1 diabetic volunteers. On September 24, 2008, we announced the beginning of this trial. On July 21, 2009 we reported positive results from this trial.

On April 21, 2009, we entered into a consulting service agreement with ADRES Advanced Regulatory Services Ltd. (“ADRES”), pursuant to which ADRES will provide services for the purpose of filing an IND application with the FDA for a Phase 2 study according to the FDA requirements. The FDA approval process and, if approved, registration for commercial use as an oral drug can take several years.

In May 2009, we commenced a non-FDA approved Phase 2B study in South Africa to evaluate the safety, tolerability and efficacy of our oral insulin capsule (ORMD0801) on type 2 diabetic volunteers. On May 6, 2010, we reported that the capsule was found to be well tolerated and exhibited a positive safety profile. No cumulative adverse effects were reported throughout this first study of extended exposure to the capsule.

On February 10, 2010, we entered into agreements with Vetgenerics Research G. Ziv Ltd., a clinical research organization, to conduct a toxicology trial on our oral insulin capsules. On March 23, 2011, we reported that we successfully completed the resulting comprehensive toxicity study for our oral insulin capsule (ORMD0801). The study was completed under conditions prescribed by the FDA Good Laboratory Practices regulations.

On September 14, 2010, we reported the successful results of an exploratory clinical trial testing the effectiveness of our oral insulin capsule (ORMD0801) in type 1 diabetes patients suffering from uncontrolled diabetes. Unstable or labile diabetes is characterized by recurrent, unpredictable and dramatic blood glucose swings often linked with irregular hyperglycemia and sometimes serious hypoglycemia affecting type 1 diabetes patients. This newly completed exploratory study was a proof of concept study for defining a novel indication for ORMD0801. We believe the encouraging results justify further clinical development of ORMD0801 capsule application toward management of uncontrolled diabetes.

We intend to file an IND application with the FDA for Phase 2 clinical studies of our orally ingested insulin during the third quarter of 2012. If we do not receive comments from the FDA on our IND application within 30 days from submission, we intend to immediately commence an FDA approved Phase 2 study to evaluate the safety, tolerability and efficacy of our oral insulin capsule (ORMD0801) on type 2 diabetic volunteers.

#### GLP-1 Analog

On September 16, 2008 we announced the launch of pre-clinical trials of ORMD0901, a GLP-1-analog. The pre-clinical trials include animal studies which suggest that the GLP-1 analog (exenatide-4) when combined with Oramed’s absorption promoters is absorbed through the gastrointestinal tract and retains its biological activity.

Glucagon-like peptide-1 (GLP-1) is an incretin hormone - a type of gastrointestinal hormone that stimulates the secretion of insulin from the pancreas. The incretin concept was hypothesized when it was noted that glucose ingested by mouth (oral) stimulated two to three times more insulin release than the same amount of glucose administered intravenously. In addition to stimulating insulin release, GLP-1 was found to suppress glucagon release (hormone involved in regulation of glucose) from the pancreas, slow gastric emptying to reduce the rate of absorption of nutrients into the blood stream, and increase satiety. Other important beneficial attributes of GLP-1 are its effects of increasing the number of beta cells (cells that manufacture and release insulin) in the pancreas and, possibly, protection of the heart.



On September 9, 2009, we received approval from the Institutional Review Board (IRB) in Israel to commence human clinical trials of an oral GLP-1 analog. The approval was granted after successful pre-clinical results were reported. The trials are being conducted on healthy volunteers at Hadassah University Medical Center in Jerusalem. Oramed's first-in-humans clinical trial is testing the safety and efficacy of ORMD-0901, an encapsulated oral GLP-1 analog formulation. The study monitored the responses of healthy males to a single dose delivered 60 minutes before a glucose load. ORMD-0901 was well tolerated by all subjects and demonstrated physiological activity, as extrapolated from ensuing subject insulin levels when compared to those observed after treatment with placebo.

#### Raw Materials

Our oral insulin capsule is currently manufactured by Swiss Caps AG, under a Clinical Trial Manufacturing Agreement.

On July 5, 2010, our subsidiary, Oramed Ltd., entered into a Manufacturing Supply Agreement ("MSA") with Sanofi-Aventis Deutschland GmbH ("sanofi-aventis"). According to the MSA, sanofi-aventis will supply our subsidiary with specified quantities of recombinant human insulin to be used for clinical trials in the United States.

The raw materials required for the manufacturing of the capsule are purchased from third parties, under separate agreements. We generally depend upon a limited number of suppliers for the raw materials. Although alternative sources of supply for these materials are generally available, we could incur significant costs and disruptions in changing suppliers. The termination of our relationships with our suppliers or the failure of these suppliers to meet our requirements for raw materials on a timely and cost-effective basis could materially adversely affect our business, prospects, financial condition and results of operations.

#### Patents and Licenses

We maintain a proactive intellectual property strategy which includes patent filings in multiple jurisdictions, including the United States and other commercially significant markets. We hold 34 patent applications currently pending with respect to various compositions, methods of production and oral administration of proteins and exenatide. Expiration dates for pending patents will fall between 2026 and 2028.

Consistent with our strategy to seek protection in key markets worldwide, we have been and will continue to pursue the patent applications and corresponding foreign counterparts of such applications. We believe that our success will depend on our ability to obtain patent protection for our intellectual property.

Our patent strategy is as follows:

- Aggressively protect all current and future technological developments to assure strong and broad protection by filing patents and/or continuations in part as appropriate;
- Protect technological developments at various levels, in a complementary manner, including the base technology, as well as specific applications of the technology; and
- Establish comprehensive coverage in the United States and in all relevant foreign markets in anticipation of future commercialization opportunities.

The validity, enforceability, written supports, and breadth of claims in our patent applications involve complex legal and factual questions and, therefore, may be highly uncertain. No assurance can be given that any patents based on pending patent applications or any future patent applications filed by us will be issued, that the scope of any patent protection will exclude competitors or provide competitive advantages to us, that any of the patents that have been or may be issued to us will be held valid or enforceable if subsequently challenged, or that others will not claim rights in or ownership of the patents and other proprietary rights held or licensed by us. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of our technology or design around any patents that have been or may be issued to us. Since patent applications in the United States are maintained in secrecy for the initial period of time following filing, we also cannot be certain that others did not first file applications for inventions covered by our pending patent applications, nor can we be certain that we will not infringe any patents that may be issued to others on such applications.

We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements. Our policy is to require our employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers, board of directors, technical review board and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific limited circumstances. We also require signed confidentiality or material transfer agreements from any company that is to receive our confidential information. In the case of employees, consultants and contractors, the agreements provide that all inventions conceived by the individual while rendering services to us shall be assigned to us as the exclusive property of our company. There can be no assurance, however, that all persons who we desire to sign such agreements will sign, or if they do, that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets or unpatentable know-how will not otherwise become known or be independently developed by competitors.

Our success will also depend in part on our ability to commercialize our technology without infringing the proprietary rights of others. No assurance can be given that patents do not exist or could not be filed which would have an adverse effect on our ability to market our technology or maintain our competitive position with respect to our technology. If our technology components, products, processes or other subject matter are claimed under other existing United States or foreign patents or are otherwise protected by third party proprietary rights, we may be subject to infringement actions. In such event, we may challenge the validity of such patents or other proprietary rights or we may be required to obtain licenses from such companies in order to develop, manufacture or market our technology. There can be no assurances that we would be able to obtain such licenses or that such licenses, if available, could be obtained on commercially reasonable terms. Furthermore, the failure to either develop a commercially viable alternative or obtain such licenses could result in delays in marketing our proposed technology or the inability to proceed with the development, manufacture or sale of products requiring such licenses, which could have a material adverse effect on our business, financial condition and results of operations. If we are required to defend ourselves against charges of

patent infringement or to protect our proprietary rights against third parties, substantial costs will be incurred regardless of whether we are successful. Such proceedings are typically protracted with no certainty of success. An adverse outcome could subject us to significant liabilities to third parties and force us to curtail or cease the development and commercialization of our technology.

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#### Partnerships and Collaborative Arrangements

We believe that working together with strategic partners will expedite product formulation, production and approval.

On February 17, 2006, we entered into an agreement with Hadasit to facilitate clinical trials and provide other services.

On October 30, 2006, we entered into a Clinical Trial Manufacturing Agreement with Swiss Caps AG (“Swiss”), pursuant to which Swiss currently manufactures the oral insulin capsule developed by us.

During April 2008, we entered into a five year master services agreement with SAFC, an operating division of Sigma-Aldrich, Inc., a leading developer, manufacturer and distributor of chemicals and biochemicals, pursuant to which SAFC is providing services for individual projects, which may include strategic planning, expert consultation, clinical trial services, statistical programming and analysis, data processing, data management, regulatory, clerical, project management, central laboratory services, pre-clinical services, pharmaceutical sciences services, and other research and development services.

On April 21, 2009, we entered into a consulting service agreement with ADRES, Advanced Regulatory Services Ltd. (“ADRES”), pursuant to which ADRES will provide services for the purpose of filing an IND application with the FDA for a Phase 2 study in accordance with FDA requirements. The FDA approval process and, if approved, registration for commercial use as an oral drug can take several years.

On July 8, 2009 we entered into an additional agreement with Hadasit, to facilitate additional clinical trials to be performed at Hadassah Medical Center in Jerusalem.

On February 10, 2010, we entered into agreements with Vetgenerics Research G. Ziv Ltd., a clinical research organization (CRO), to conduct a toxicology trial on our oral insulin capsules.

On May 2, 2010, we entered into an additional agreement with SAFC Pharma, a division of the Sigma-Aldrich, to develop a process to produce one of our oral capsule ingredients.

On July 5, 2010, our subsidiary, Oramed Ltd., entered into an MSA with Sanofi-Aventis. Pursuant to the MSA, Sanofi-Aventis will supply our subsidiary with specified quantities of recombinant human insulin to be used for clinical trials in the United States.

On May 13, 2011, we entered into a consulting agreement with a third party for a period of 12 months, pursuant to which such consultant will provide investor relations services and will be entitled to a cash monthly fee of \$4,000, that may be increased up to \$10,000 upon the completion of a \$5,000,000 capital raise by us. In addition, the consultant received a warrant to purchase up to 32,000 of our shares. The warrant has a term of five years and an exercise price of \$0.50 per share and will vest in 12 installments during the period from October 2011 to May 2016.

On August 15, 2011, we entered into a consulting agreement with a third party for a period of nine months, pursuant to which such consultant will provide investor relations services and will be entitled to a cash monthly fee of \$4,000, and an additional \$3,000 in the first month. In addition, the consultant will be issued 249,000 of our shares in three installments over the engagement period, commencing November 2011.

#### Out-Licensed Technology

On June 1, 2010, our subsidiary, Oramed Ltd., entered into a joint venture agreement with D.N.A Biomedical Solutions Ltd. (formerly Laser Detect Systems Ltd), an Israeli company listed on the Tel Aviv Stock Exchange ("D.N.A"), for the establishment of a new company to be called Entera Bio Ltd. ("Entera").

Under the terms of a license agreement that was entered into between Oramed and Entera in August 2010, we out-licensed technology to Entera, on an exclusive basis, for the development of oral delivery drugs for certain indications to be agreed upon between the parties. The out-licensed technology differs from our main delivery technology that is used for oral insulin and GLP-1 analog and is subject to different patent applications. Entera's initial development effort is for an oral formulation for the treatment of osteoporosis. The license was royalty-free unless our ownership interest in Entera decreased to 30% or less of its outstanding share capital, in which case royalties would have been payable with respect to revenues derived from certain indications. Under certain circumstances, Entera may have received ownership of the licensed technology, in which case we would have received a license back on the same terms.

D.N.A initially invested \$600,000 in Entera, and Entera was initially owned in equal parts by Oramed and D.N.A. Entera's Chief Executive Officer, Dr. Phillip Schwartz, was granted options to purchase ordinary shares of Entera, reflecting 9.9% of Entera's share capital, upon full exercise.

On March 31, 2011, we consummated a transaction with D.N.A, whereby we sold to D.N.A 47% of Entera's outstanding share capital on an undiluted basis. As consideration for the Entera shares, we received a promissory note issued by D.N.A in the principal amount of \$450,000, with an annual interest rate of 0.45%, to be paid within four months after closing, and 8,404,667 ordinary shares of D.N.A, having an aggregate market value of approximately \$581,977 as of March 31, 2011. The promissory note was secured by a personal guarantee of the D.N.A majority shareholders and its term was extended by an Addendum to the Share Purchase agreement dated August 11, 2011. D.N.A paid the promissory note on November 14, 2011. The ordinary shares of D.N.A were restricted for six months from the closing. In addition, D.N.A invested \$250,000 in our private placement investment round, which closed on February 22, 2011, for which it received 781,250 shares of our common stock and five-year warrants to purchase 273,438 shares of common stock at an exercise price of \$0.50 per share.

As part of the transaction with D.N.A, we entered into a patent transfer agreement (to replace the original license agreement upon closing) pursuant to which Oramed assigned to Entera all of its right, title and interest in and to the patent application that it had licensed to Entera in August 2010. Under this agreement, our subsidiary, Oramed Ltd., is entitled to receive from Entera royalties of 3% of Entera's net revenues (as defined in the agreement) and a license back of that patent application for use in respect of diabetes and influenza.

On the closing date, Oramed, Entera and D.N.A terminated the joint venture agreement entered into on June 1, 2010 in connection with the formation of Entera.

In September 2011, Entera reported successful Phase 1 clinical trial results. We believe the Phase 1 data supports the continued development of Entera's oral osteoporosis drug. The Phase 1 clinical trial consisted of twelve healthy patients and was conducted at the Hadassah Medical Center in Jerusalem. No adverse events were reported.

## Results of Operations

### Going concern assumption

The accompanying financial statements have been prepared assuming that we will continue as a going concern. We have net losses for the period from inception (April 12, 2002) through November 30, 2011 of \$15,025,802, as well as negative cash flow from operating activities. Based upon our existing spending commitments, estimated at \$4.9 million for the twelve months following November 30, 2011, and our cash availability, we do not have sufficient cash resources to meet our liquidity requirements through November 30, 2012. Accordingly, these factors raise substantial doubt about our ability to continue as a going concern. Management is in the process of evaluating various financing alternatives as we will need to finance future research and development activities and general and administrative expenses through fund raising in the public or private equity markets. Although there is no assurance that we will be successful with those initiatives, management believes that it will be able to secure the necessary financing as a result of ongoing financing discussions with third party investors and existing shareholders.

The financial statements do not include any adjustments that may be necessary should we be unable to continue as a going concern. Our continuation as a going concern is dependent on our ability to obtain additional financing as may be required and ultimately to attain profitability.

### Critical accounting policies

Our significant accounting policies are more fully described in the notes to our consolidated financial statements included in our annual report filed on Form 10-K. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepared in accordance with U.S. generally accepted accounting principles. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.





Marketable securities: Consist mainly of equity securities classified as available-for-sale and are recorded at fair value. The fair value of the restricted securities is measured based on the quoted prices of the otherwise identical unrestricted securities, adjusted for the effect of the restriction by applying a proper discount. The discount was determined with reference to other similar restricted instruments. Similar securities, with no restriction on tradability, are quoted on an active market. Changes in fair value, net of taxes, are reflected in other comprehensive income (loss).

Factors considered in determining whether a loss is temporary include the extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee based on our intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. The loss is recorded as a charge to earnings.

Valuation of options and warrants: We granted options to purchase shares of our common stock to employees and consultants and issued warrants in connection with some of our financings.

We account for share-based payments in accordance with the guidance that requires awards classified as equity awards be accounted for using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period, net of estimated forfeitures. We estimated forfeitures based on historical experience and anticipated future conditions.

We elected to recognize compensation cost for an award with only service conditions that has a graded vesting schedule using the accelerated method based on the multiple-option award approach.

When stock options are granted as consideration for services provided by consultants and other non-employees, the transaction is accounted for based on the fair value of the consideration received or the fair value of the stock options issued, whichever is more reliably measurable, pursuant to the guidance. The fair value of the options granted is measured on a final basis at the end of the related service period and is recognized over the related service period using the straight-line method.

Taxes on income: Deferred taxes are determined utilizing the asset and liability method based on the estimated future tax effects of differences between the financial accounting and tax bases of assets and liabilities under the applicable tax laws. Deferred tax balances are computed using the tax rates expected to be in effect when those differences reverse. A valuation allowance in respect of deferred tax assets is provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. We have provided a full valuation allowance with respect to its deferred tax assets.

Regarding our subsidiary, Oramed Ltd., the guidance prohibits the recognition of deferred tax liabilities or assets that arise from differences between the financial reporting and tax bases of assets and liabilities that are measured from the local currency into dollars using historical exchange rates, and that result from changes in exchange rates or indexing for tax purposes. Consequently, the abovementioned differences were not reflected in the computation of deferred tax assets and liabilities.

Comparison of three month period ended November 30, 2011 and 2010

The following table summarizes certain statements of operations data for the Company for the three month period ended November 30, 2011 and 2010:

| Operating Data:                            | Three months ended   |                      |
|--|----------------------|----------------------|
|  | November<br>30, 2011 | November<br>30, 2010 |
| Research and development costs, net        | \$184,016            | \$286,488            |
| General and administrative expenses        | 281,901              | 315,129              |
| Financial expenses, net                    | 12,602               | 1,167                |
| Net loss for the period                    | \$478,519            | \$602,784            |
| Loss per common share – basic and diluted  | \$(0.01 )            | \$(0.01 )            |
| Weighted average common shares outstanding | 70,104,583           | 57,932,597           |

#### Research and development expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, costs of registered patents materials, supplies, the cost of services provided by outside contractors, including services related to our clinical trials, clinical trial expenses, the full cost of manufacturing drug for use in research, preclinical development. All costs associated with research and development are expensed as incurred.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as contract research organizations, independent clinical investigators, and other third-party service providers to assist us with the execution of our clinical studies.

Clinical activities which relate principally to clinical sites and other administrative functions to manage our clinical trials are performed primarily by contract research organizations ("CROs"). CROs typically perform most of the start-up activities for our trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management.

Clinical trial and pre-clinical trial expenses include regulatory and scientific consultants' compensation and fees, research expenses, purchase of materials, cost of manufacturing of the oral insulin capsules, payments for patient recruitment and treatment, costs related to the maintenance of our registered patents, costs related to the filings of patent applications, as well as salaries and related expenses of research and development staff.

In August 2009, Oramed Ltd., our wholly owned Israeli subsidiary, was awarded a government grant amounting to a total net amount of New Israeli Shekels ("NIS") 3.1 million (approximately \$813,000), from the Office of the Chief Scientist of the Ministry of Industry, Trade and Labor of Israel (the "OCS"). This grant was used for research and development expenses for the period of February 2009 to June 2010. The funds were used by us to support further research and development and clinical study of our oral insulin capsule and Oral GLP-1-analog. In December 2010, Oramed Ltd., was awarded another grant amounting to a total net amount of NIS 2.9 million (approximately \$807,000) from the OCS, which was designated for research and development expenses for the period of July 2010 to November 2011. We used the funds to support further research and development and clinical study of our oral insulin capsule and Oral GLP-1-analog. The two grants are subject to repayment according to the terms determined by the

OCS and applicable law. See "--Government Grants" below.

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During the three months ended November 30, 2011, research and development expenses totaled \$184,016, compared to \$286,488 for the three months ended November 30, 2010. The decrease is mainly attributable to a temporary decrease in clinical trials costs and other related expenses, due to a delay in development and production of materials by a third party contractor, which are necessary for proceeding with such clinical trials. The research and development costs include stock based compensation costs, which during the three months ended November 30, 2011, totaled \$24,605 as compared to \$94,669 during the three months ended November 30, 2010.

#### Government Grants

In the three months ended November 30, 2011 and 2010, we recognized research and development grants in an amount of \$41,257 and \$151,976, respectively. As of November 30, 2011, we had no contingent liabilities to the OCS.

#### Grants from Bio-Jerusalem

We are committed to pay royalties to Bio-Jerusalem fund on proceeds from future sales at a rate of 4% and up to 100% of the amount of the grant received by the Company (Israeli CPI linked) in the total amount of \$52,733. As of November 30, 2011, we had not yet realized any revenues from the said project and did not incur any royalty liability.

For the three months period ended November 30, 2011, there were no grants received from the Bio-Jerusalem fund.

#### General and administrative expenses

General and administrative expenses include the salaries and related expenses of our management, consulting costs, legal and professional fees, traveling, business development costs, insurance expenses and other general costs.

For the three months ended November 30, 2011, general and administrative expenses totaled \$281,901 compared to \$315,129 for the three months ended November 30, 2010. Costs incurred related to general and administrative activities during the three months ended November 30, 2011 reflect an increase in investor relations' consulting expenses resulting from the Company's efforts to raise funds, which were offset by a decrease in stock based compensation expenses. During the three months ended November 30, 2011, as part of our general and administrative expenses, we incurred \$26,691 related to stock options granted to employees and consultants, as compared to \$100,632 during the three months ended November 30, 2010.

#### Financial income/expense, net

During the three months ended November 30, 2011, we generated a larger interest income on available cash and cash equivalents balance than in the previous period, this income was offset by bank charges.

#### Liquidity and Capital Resources

From inception through November 30, 2011, we incurred losses in an aggregate amount of \$15,025,802. We have financed our operations through the private placements of equity and debt financing, raising a total of \$11,655,693, net of transaction costs. We will seek to obtain additional financing through similar sources. As of November 30, 2011, we had \$1,495,615 of available cash as well as \$1,805,030 in short term interest bearing investments. We anticipate that we will require approximately \$4.9 million to finance our activities during the twelve months following November 30, 2011.

Management is in the process of evaluating various financing alternatives as we will need to finance future research and development activities and general and administrative expenses through fund raising in the public or private equity markets. Although there is no assurance that we will be successful with those initiatives, management believes that it will be able to secure the necessary financing as a result of ongoing financing discussions with third party investors and existing shareholders as well as through additional funding from the OCS.

During fiscal years 2010 and 2011 we issued a total of 927,387 shares of common stock to various third party vendors for services rendered. The aggregate value of those shares was approximately \$290,529. We also consummated a private placement by selling 937,500 "units" at a purchase price of \$0.32 per unit for a total consideration of \$300,000. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.35 of a share of common stock at an exercise price of \$0.50 per share.

#### Employee's and Consultant's Stock Options and Warrants

No options or warrants were granted to employees or consultants during the three month period ended November 30, 2011.

#### Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

## Planned Expenditures

The estimated expenses referenced herein are in accordance with our business plan. Since our technology is still in the development stage, it can be expected that there will be changes in some budgetary items. Our planned expenditures for the twelve months beginning December 1, 2011 are as follows:

| Category:  | Amount      |
|--|-------------|
| Research and development costs, net of OCS funds | \$4,028,000 |
| General and administrative expenses              | 898,000     |
| Financial income, net                            | 1,000       |
| Taxes on income                                  | -           |
| Total  | \$4,925,000 |

As previously indicated, we are planning to conduct further clinical studies as well as file an IND application with the FDA for our orally ingested insulin during the third quarter of 2012. We expect to have a significant increase in research and development expenses as a result of preparation for the FDA approved Phase 2 study that will follow the IND filing, and during the term of the study. Our ability to proceed with these activities is dependent on several major factors including the ability to attract sufficient financing on terms acceptable to us and receiving additional grant from the OCS.

## Employment and Consulting Agreements

We have not engaged in any employment and consulting agreements during the three month period ended November 30, 2011.

### ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide the information required by this Item.

### ITEM 4 - CONTROLS AND PROCEDURES

#### Disclosure Controls and Procedures

Our management, including our chief executive officer and chief financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of November 30, 2011. Based on such review, our chief executive officer and chief financial officer have determined that in light of their conclusion with respect to the effectiveness of our internal control over our financial reporting as of such date, that the Company did not have in place effective controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure, and is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms.

#### Changes in Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting identified in connection with the evaluation thereof that occurred during the three months ended November 30, 2011 that have materially affected, or are reasonable likely to materially affect our internal control over financial reporting.



## PART II - OTHER INFORMATION

### ITEM 1 - LEGAL PROCEEDINGS

From time to time we may become subject to litigation incidental to our business. We are not currently a party to any material legal proceedings.

### ITEM 2 - UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

There were no unregistered sales of our equity securities during the three month period ended November 30, 2011.

### ITEM 6 - EXHIBITS

| Number | Exhibit  |
|--------|--|
| (3)    | Articles of Incorporation and By-laws  |
| 3.1    | Certificate of Incorporation (incorporated by reference from our Current Report on Form 8-K filed March 14, 2011).   |
| 3.2    | Bylaws (incorporated by reference from our Current Report on Form 8-K filed on March 14, 2011).  |
| 3.3    | Articles of Merger filed with the Nevada Secretary of State on March 29, 2006 (incorporated by reference to our Current Report on Form 8-K filed on April 10, 2006).         |
| 3.4    | Articles of Conversion filed with the Nevada Secretary of State on March 8, 2011 (incorporated by reference to our Current Report on Form 8-K filed on March 14, 2011).      |
| 3.5    | Certificate of Conversion filed with the Delaware Secretary of State on March 8, 2011 (incorporated by reference to our Current Report on Form 8-K filed on March 14, 2011). |
| (4)    | Instruments defining rights of security holders, including indentures  |
| 4.1    | Specimen Stock Certificate (incorporated by reference from our Registration Statement on Form S-1, filed on March 25, 2011).   |
| 4.2    | Form of warrant certificate (incorporated by reference from our current report on Form 8-K filed on June 18, 2007).  |
| (31)   | Section 302 Certification  |
| 31.1 * | Certification Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.  |
| 31.2 * | Certification Statement of the Principal Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.   |
| (32)   | Section 906 Certification  |
| 32.1 * | Certification Statement of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act Of 2002.         |
| 32.2 * | Certification Statement of the Principal Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act Of 2002.        |

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Filed herewith

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ORAMED PHARMACEUTICALS INC.  
Registrant

Date: January 11, 2012

By: /s/ Nadav Kidron  
Nadav Kidron  
President, Chief Executive Officer and Director

Date: January 11, 2012

By: /s/ Yifat Zommer  
Yifat Zommer  
Chief Financial Officer

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